



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/550,471	FIRST NAMED APPLICANT Elliot Ehrich	ATTY. DOCKET NO. 2685.3002 US
---	--	----------------------------------

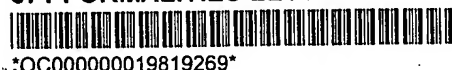
INTERNATIONAL APPLICATION NO. PCT/US03/27618	
I.A. FILING DATE 09/04/2003	PRIORITY DATE 03/19/2003

38421  
 ELMORE PATENT LAW GROUP, PC  
 209 MAIN STREET  
 N. CHELMSFORD, MA 01863

**RECEIVED**  
 AUG 08 2006

BY: .....

CONFIRMATION NO. 4421  
 371 FORMALITIES LETTER



\*OC000000019819269\*

Date Mailed: 08/03/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/22/2005
- Copy of the International Search Report filed on 09/22/2005
- Preliminary Amendments filed on 09/22/2005
- Information Disclosure Statements filed on 12/06/2005
- Request for Immediate Examination filed on 09/22/2005
- U.S. Basic National Fees filed on 09/22/2005
- Priority Documents filed on 09/22/2005
- Specification filed on 09/22/2005
- Claims filed on 09/22/2005
- Abstracts filed on 09/22/2005
- Drawings filed on 09/22/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

**Docketed**  
 By *IMD*

Total additional fees required for this application is **\$430** for a Large Entity:

- **\$130 Surcharge.**

- This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application** and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- The application search fee has not been paid. Applicant must submit **\$100** to complete the search fee. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- The application examination fee has not been paid. Applicant must submit **\$200** to complete the examination fee for a non-small entity. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

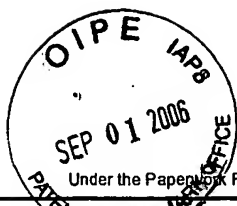
---

Telephone: (703) 308-9140 EXT 217

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/550,471	PCT/US03/27618	2685.3002 US

FORM PCT/DO/EO/905 (371 Formalities Notice)



IAP6 Rec'd PCT/PTO 01 SEP 2006 PCT

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>2685.3002 US</b>
		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/550,471</b>
INTERNATIONAL APPLICATION NO. <b>PCT/US2003/27618</b>	INTERNATIONAL FILING DATE <b>04 SEPT 2003</b>	PRIORITY DATE CLAIMED <b>19 March 2003</b>
TITLE OF INVENTION <b>Trospium Containing Compositions</b>		
APPLICANT(S) FOR DO/EO/US <b>Elliot Ehrich, Daniel Deaver, Robert Clarke, Michael M. Lipp</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/550,471</b>		INTERNATIONAL APPLICATION NO. <b>PCT/US2003/27618</b>		ATTORNEY'S DOCKET NUMBER <b>2685.3002 US</b>	
20. Other items or information: <b>Return Postcard Receipt, Statement under 3.73(b) including a copy of the Assignment and a Reply in regards to the Sequence Listing.</b>					
The following fees have been submitted				<b>CALCULATIONS</b>	<b>PTO USE ONLY</b>
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... <b>\$300</b>				\$	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... <b>\$0</b> All other situations..... <b>\$200</b>				\$ 200	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... <b>\$0</b> Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... <b>\$100</b> International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... <b>\$400</b> All other situations..... <b>\$500</b>				\$ 100	
<b>TOTAL OF 21, 22 and 23 =</b>				<b>\$ 300</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is <b>\$250</b> for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of <b>\$130.00</b> for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 130	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				\$	
Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 430</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 430</b>	
				Amount to be refunded:	\$
				Amount to be charged	\$ 430

09/07/2006 MKAYPAGH 00000041 502807 10550471

 01 FC:1683 200.00 DA  
 02 FC:1681 100.00 DA  
 03 FC:1687 130.00 DA


Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 502807 in the amount of \$ 430 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit  
Account No. 502807 A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not  
be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed  
and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 38421  
ELMORE PATENT LAW GROUP, PC  
209 Main Street  
N Chelmsford, MA 01863



SIGNATURE

Carolyn S. Elmore, Esq.

NAME

37,567

REGISTRATION NUMBER



Docket No: 2685.3002 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Elliot Ehrich, Daniel Deaver, Robert Clarke and Michael M. Lipp

Application No: 10/550,471                      Group No: 1614

371 Date: Not Assigned                      Examiner: Not Assigned

Confirmation No.: 4421

Title: Trospium Containing Compositions

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<i>Hollie Wakefield</i>	<i>8-29-06</i>
Signature	Date
<b>HOLLIE WAKEFIELD</b>	
Typed or printed name of person signing certificate	

**REPLY**

Mail Stop NTFMR  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is a Reply to the Notification of Missing Requirements under 35 USC 371 dated August 3, 2006.

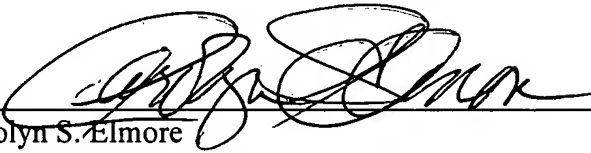
The Notification notes that the oath or declaration, surcharge, search fees and examination fee must be submitted. These fees and documents are being filed herewith.

Additionally, the Notification requests the submission of a Sequence Listing. However, the undersigned is unable to identify any sequences in the application. The abbreviations located at, for examples, page 15, line 18 do not describe peptides or DNA sequences, but rather chemically unrelated molecules. As such, it is respectfully requested that the requirement to file a Sequence Listing be withdrawn.

10/550,471

Respectfully submitted,

ELMORE PATENT LAW GROUP, P.C.

By   
Carolyn S. Elmore

Registration No.: 37,567

Telephone: (978) 251-3509

Facsimile: (978) 251-3973

N. Chelmsford, MA 01863

Dated: 8/29/06